UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Note to Reader
September 9, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply, EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, if unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues

available in the information in this docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack Housenger, Acting Director
Special Review and Reregistration
Division

08/OPP #34132

Gowan

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May 1, 1998

Walter I. Waldrop, Chief
Reregistration Branch III
Special Review and Reregistration Division (H7508W)
Office of Pesticide Programs
U. S. Environmental Protection Agency
401 M Street, S. W.
Washington, DC 20460

Dear Mr. Waldrop:

Subject: Bensulide: Chemical No. 9801, Case No. 2035
FIFRA 1988 Accelerated Reregistration Program
Human Health Effects Draft RED Chapter

Thank you for your letter of March 26 and the draft RED chapter, which we received on April 1. We appreciate the Agency's efforts to prepare an objective evaluation of bensulide, and we thank the Agency for the opportunity to offer the following comments and clarifications. In a number of cases we have come to conclusions which differ from the Agency's. In the discussion below it will be seen that this is often due to our belief that the Agency's standard assumptions are not applicable for reasons which specifically involve the properties or commercial use patterns of bensulide.

In a few instances the Agency has assumed uses which are broader than those which actually occur commercially. We acknowledge that such uses are not prohibited by the labels. The Agency may think it appropriate to initiate certain label restrictions in order to assure itself that such uses do not occur in the future. In almost every case these use patterns involve turf. Several other companies hold independent registrations for turf products, so Gowan cannot unilaterally propose label restrictions to the Agency. We are in the process of discussing potential label changes with the companies who sell bensulide products on turf, but we cannot comment further at this time.

Our responses below follow the order in which comments were presented in the draft RED chapter.

RED pp. 7 - 29 (Hazard Assessment and Dose Response sections): We believe that the Agency's review of the toxicology database for bensulide was well done. We have no specific comments regarding this review and we commend the Agency's efforts.

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90-Day Rat Neurotoxicity Study:
The Agency's June, 1991 Response to Phase 3 Submission included a request for a 90-day rat neurotoxicity study (Guideline No. 82-7 SS, renumbered 82-5(b)). Our letter of October 27, 1992 confirmed a discussion with the Agency, noting that the Agency was still in the process of developing guidelines for the study. The Agency in a letter dated June 4, 1993 required the submission and approval of a protocol before the study could begin. Gowan submitted a protocol for the study on September 22, 1993. Our letter of April 27, 1994 noted that unless the Agency reviewed the protocol soon, we would be unable to meet the deadline of March 31, 1995 for this study. Our annual reports of March 15, 1994, March 27, 1995, March 7, 1996 and March 18, 1997 noted that we were still awaiting the Agency's comments.

The Hazard Identification Committee issued a report on bensulide on July 31, 1997. The Agency reviewed an acute neurotoxicity study in rats, but there was no mention of the need for a 90-day rat neurotoxicity study. Similarly, the HED's draft RED chapter on human health effects dated March 3, 1998 did not mention the need for this study.

We conclude that the Agency does not need this study in order to effectively evaluate bensulide, and we believe that this study would provide no new information of significance. Therefore, Gowan Company respectfully requests a waiver from the requirement for a 90-day rat neurotoxicity study.

Dermal Absorption:
On the basis of the available information, the Agency has made an assumption regarding the dermal absorption of bensulide. This figure may be somewhat high, and we wish to reserve the right to provide more definitive information in the future if the circumstances warrant such further work.

RED p. 37, par. 7 (dietary risk assessment):
"Use of the reassessed tolerances...results in the following MOEs:

U.S. General Population = 3751
Infants (<1 year) = 1500
Children (1 to 6 years) = 1500

These MOEs do not exceed the HED's level of concern...."

Gowan Response:
In a Tier 1 acute analysis, we obtained results similar to the Agency's:

U.S. General Population = 5051
Non-Nursing Infants (<1 year) = 3843
Children (1 to 6 years) = 3144

In a Tier 2 analysis in which the percent crop treated is considered, however, we obtain MOEs which are well above 100,000 for all population subgroups. Full details are presented in Appendix 1. A Monte Carlo analysis, which we have not conducted, would produce even more favorable MOEs.

Information on the percent of crops treated was presented to the Agency in Table 2 of our submission of May 8, 1997. Gowan Company considers this information to be **CONFIDENTIAL BUSINESS INFORMATION**, and the acute analyses in Appendix 1 are also contain **CONFIDENTIAL BUSINESS INFORMATION.**

Of course, the differences between the Agency's calculations and our own are of no practical significance at this time. However, we assume that the Agency will eventually include bensulide in a cumulative risk assessment with nearly 40 other organophosphate products, and we feel that such differences might become of greater importance in the future.

RED p. 41, par. 3 (assumptions used in the occupational exposure assessment): "Average work day interval represents an 8 hour workday...."

Gowan Response:
We believe that agricultural workers or turf applicators will almost never apply bensulide as much as 8 hours per day. The reasons for our belief are explained in the following section:

RED p. 41, par. 4 (assumptions used in the occupational exposure assessment):

"Daily areas and volumes...to be treated in each scenario include [several assumptions follow]."

Gowan Response:
We believe that the Agency's standard assumptions regarding the area treated are in some cases not applicable to bensulide.

Golf courses: the Agency's estimates are at least an order of magnitude too high. To our knowledge, bensulide is used virtually entirely on golf greens, and a small amount may be used on tees. It is not used on fairways because the product is too expensive. This observation was noted elsewhere in the draft RED [p. 39, par. 1]. Most greens have a radius of 30 feet or less, but we will assume an upper limit of 50 feet. In this case, all of the greens on an 18-hole course would have a total area of 3.2 acres. If tees were also treated, which is extremely unlikely, the total treated area would approximately double, to 6 - 7 acres. This is far less than the Agency's assumption of 50 acres treated by professional turf applicators and 40 acres for granular tractor-drawn spreaders. The risk to such applicators is correspondingly an order of magnitude lower than what the Agency has calculated.

It may be noted that golf course superintendents are highly-paid employees of the

golf course in question. These people rarely if ever treat more than one golf course, and their occupational exposure to bensulide is correspondingly limited.

There are approximately 14,000 golf courses in the United States. Approximately 40% of these have 9 holes and approximately 50% have 18 holes. Only about 10% of all golf courses have 36 or more holes. It is our understanding that no single individual treats more than 36 holes. In the few resort complexes which have more than 36 holes, responsibility for turf management is handled by more than one individual.

It is our understanding that a label statement restricting the use of bensulide on golf courses to the greens and tees only would have little or no impact upon the current use of such products. Such a restriction would enable the Agency to reduce its estimates of occupational and non-occupational exposures from golf courses. Gowan cannot directly propose such an amendment to the Agency because all products which are actively sold for use on golf courses are registered by other companies (PBI/Gordon Corporation, The Scotts Company and United Horticultural Supply and/or its affiliated company Platte Chemical Company).

Other professional applications: A small portion of all bensulide use (less than 2 percent and, to our knowledge, possibly none at all) involves application by professional applicators who treat home lawns and public areas. The Agency has assumed that up to 5 acres per day may be treated with granular products using push-type granular spreaders or "bellygrinder" applicators, and 5 acres may be treated with EC products using backpack applicators.

Bensulide is no longer a product of choice by professional lawn care companies because of the development of new and less expensive products during the last decade. Assuming that a professional applicator does use bensulide, however, such an applicator would treat areas this large with mechanized equipment. Granular products are normally applied using a spreader pulled by a small garden tractor, and EC products are normally applied using a ground boom for larger areas or a low-pressure hand wand connected to a truck-mounted tank for smaller areas. Treatment of large areas by hand equipment would be an inefficient and unprofitable use of manpower because these application techniques are slower than applications using mechanized equipment. We are told that one acre is a reasonable upper limit to assume for push-type spreaders and backpack sprayers, and "bellygrinders" are almost never used by professional applicators.

Chemigation (agricultural) applications: to our knowledge, the largest area which has been treated with bensulide at one time is 80 acres, not 350 acres, and this occurred only in the desert Southwest. Elsewhere, the maximum area treated is thought to be 40 acres.

Furthermore, for large treatment areas, Prefar 4-E Herbicide is transported and distributed in bulk containers, not in the standard 2.5-gallon jugs. This greatly

reduces the exposure of pesticide handlers. Bulk containers constitute a closed system, and the applicator makes only one connection from the bulk tank to the irrigation system. There is no "mixer/loader" in a chemigation system using a bulk container.

The Agency noted elsewhere in the RED [p. 38, last line] that PHED exposure estimates for bulk handling are unfortunately not available. We agree, but we do not believe that this warrants using default assumptions (e.g., handling 210 2.5-gallon jugs of Prefar 4-E to treat 350 acres) which are known to be incorrect.

RED p. 41, par. 5 (application rates)
"...No use data were provided by the registrant concerning the actual application rates that are commonly used for bensulide."
and
RED p. 60, last par.
"...No use data were provided by the registrant concerning actual application rates...."

Gowan Response:
We confirm that the Agency's assumptions about maximum application rates are correct. Many applications are made at the maximum application rates of 6 lb a.i./A for agricultural uses and 12.5 lb a.i./A for turf uses. Chemigation rates are normally 4 - 5 lb a.i./A. In practice, the minimum necessary application rates even under optimal conditions are approximately 60 percent of the maximum labeled rates.

RED pp. 47 - 51 (Table 7: Short-Term Dermal Risks from Bensulide and Table 8: Intermediate-Term Dermal Risks from Bensulide): [various scenarios are addressed, based upon exposure calculations in Table 6].

Gowan Response:
The Agency did not calculate acute dermal risks from bensulide, but we believe that this is the most relevant measure of risk. The majority of mixers, loaders and applicators (agricultural workers) will not be exposed to bensulide more than one day per year. Some golf course superintendents may be exposed two days per year, with months in between applications, and a few may make three applications of bensulide.

Agricultural workers involved in chemigation may be exposed a few consecutive days per year but less than a week. Similarly, commercial lawn care personnel may apply bensulide over a few consecutive days within the very narrow window in early spring when the application of bensulide is feasible. These are the only two groups, in our opinion, for which the evaluation of short-term risk is appropriate.

No user population is exposed to bensulide 7 or more consecutive days per year. It

should also be noted that while "short-term" is normally defined as 7 days or less, the bensulide short-term NOEL is derived from a developmental study involving 14 consecutive days of expcsure [cf. RED, Table 3, p. 29].

The Agency's calculation of intermediate-term risk (Table 8) is therefore inappropriate and irrelevant to the assessment of actual occupational risk. We suggest that Table 8 be removed from the RED.

Given our comments above regarding treated areas, we wish to make the following observations on the Agency's calculation of short-term risk from various scenarios. We will only address maximum application rates.

Mixing/loading liquids for chemigation: assuming the use of PPE (long pants and long-sleeved shirt) and engineering controls (chemical-resistant gloves), the Agency calculated and MOE of 87 for this activity. Using our maximum acreage assumption (80 vs. the Agency's 350), we calculate an MOE of 380. The use of bulk containers rather than the standard 2.5-gallon jugs constitutes a closed system and makes the chemigation of large areas the safest of all scenarios considered by the Agency.

Other mixing/loading scenarios: no comment is necessary since the Agency calculates adequate MOEs with or without PPE. We have no objection to adding PPE to the labels.

Applicator scenarios: no comment is necessary since the Agency calculated adequate MOEs without PPE.

Mixer/loader/applicator risk:

> low-pressure and high-pressure hand wands and backpack sprayer: these scenarios would apply only to commercial applicators since the EC formulations are not available to homeowners. The Agency has assumed that up to 5 acres might be treated in a day. The Agency, by also calculating short-term risk, is also assuming that the applicator may treat this area for up to seven consecutive days, or 35 acres per week. (Please refer to the definition of "short-term" on page 29 of the RED. The short-term NOEL for bensulide was actually derived from 14 consecutive days of dosing in a developmental study.) We believe that these scenarios are unrealistic because they all involve a very inefficient use of manpower. The commercial applicators of whom we are aware use a truck-mounted "nurse tank" and a low-pressure/high-volume handgun.
>
> Furthermore, the scenario using a high pressure hand wand is not realistic because: (1) high pressure is unnecessary to distribute the spray solution evenly and (2) high pressure favors drift, which is highly undesirable with most herbicides. We do not believe that bensulide is applied using a high-

pressure hand wand, and we would not object to a label restriction against this method of application.

low-pressure/high-volume handgun on turf: the Agency has calculated an adequate MOE for this scenario.

push-type granular spreader: the Agency calculated a minimum MOE of 37, assuming that 5 acres are treated. We believe, however, that an area as large as 5 acres will be treated by a tractor-drawn spreader, for which an adequate MOE has been calculated. We believe it highly unlikely that an area larger than 1.5 acres would be treated using a push-type spreader, in which case the MOE would be greater than 100.

"bellygrinder": to our knowledge, bensulide is not applied by bellygrinders. It is our understanding that Green Light (the only company to whom this scenario applies) would not object to a label restriction against the use of bellygrinders.

RED p. 59, par.1 (post-application and assumptions):
"...further information pertaining to the use of bensulide and any cultural practices associated with the crops in question should be provided in order for HED to assess any scenarios where there is exposure potential...."

Gowan Response:
We appreciate the opportunity to offer the following clarifications:

Bensulide is not applied aerially. We acknowledge that this is not stated on the label, and we would be willing to amend the label to clarify this point.

The agricultural use of bensulide entails application before planting, or after planting but before the crop emerges from the soil.

Bensulide is not used on sod farms.

RED p. 59, par. 2 (exposure scenarios):
"HED evaluated bensulide use patterns in the ornamental and residential marketplaces and determined that there are likely post-application exposures...."

Gowan Response:
The discussion above regarding use only on golf course greens is applicable here. The treated area to which golfers are exposed is much smaller than what the Agency has assumed, and dermal exposure will be correspondingly reduced.

RED p. 60, par. 5 (transferable residue data):
"Due to a lack of chemical-specific transferable residue data (TR), a surrogate

approach has been used...Available residues on application day are assumed to be 20 percent of the application rate and the residues are assumed to decline at a rate of 10 percent per day."

Gowan Response:
It is true that data specific to bensulide do not currently exist. However, a dislodgeable residue dissipation study on turf is scheduled to begin this month. The study duration is only 35 days, so a report is expected to be available later this year. (This study is not due under the Outdoor Residential DCI until October, 1999.) We will of course submit this information to the Agency as soon as possible in order to permit a more precise exposure and risk determination.

We believe that our study will demonstrate initial residue levels much below those which would normally be predicted because of the requirement that all applications on turf must be immediately watered into the soil in order for bensulide to be herbicidally effective. Irrigation involves either washing an EC formulation off the surface of the grass leaves, or disintegrating a granular formulation and washing any associated dust into the soil. We expect that initial residues after irrigation will be at least an order of magnitude below the Agency's estimate of 20% of applied residues.

It was not clear from the Agency's discussion whether the assumption of a 10 percent reduction per day in residues involved first-order or zero-order kinetics. However, Tables 11 and 12 (RED pp. 63 - 66) show that the Agency assumed first-order kinetics and carried out some calculations past 60 days.

If the Agency had assumed zero-order kinetics rather than first-order kinetics, all residues would be gone after 10 days. It is our belief that zero-order kinetics more accurately model actual residues on turf grass than first-order residues. Our reason is very simple: grass is mowed.

In golf courses, bentgrass greens are normally kept very short, 1/8 to 3/16 inch high. These greens are normally mowed every single day during the seasons when the grass is actively growing. Golf course tees are similarly cared for, and the grass is only slightly higher, 1/4 to 3/8 inch. The cut grass is bagged and removed from the premises because short, valuable, highly visible, high-traffic, highly ornamental grass is not compatible with the practice of mulching during mowing. The treated leaf mass is therefore rapidly removed from these areas and is soon completely replaced by untreated grass. We do not believe that there is any reasonable expectation that untreated grass will contain significant transferable surface residues.

In other areas such as home lawns the rate of residue decline is expected to be somewhat slower since the grass is kept higher, and therefore a longer time is required for all of the treated grass to grow out.

RED p. 61, par. 1 (exposure data):
"Due to a lack of scenario-specific exposure data, HED has calculated unit exposure values...."

Gowan Response:
Gowan was not able to reconstruct the Agency's calculations. We request a copy of HED's detailed calculations.

The Agency is aware that Gowan is a member of the industry Outdoor Residential Exposure Task Force. We wish to bring to your attention an update on the progress of ORETF which was presented to the Scientific Advisory Panel on March 25, 1998. The following statements were made:

> "...The ORETF initiated its research program almost 2 years prior to the enactment of FQPA. With the advent of FQPA, the overall scope and complexity of the research program has markedly increased, resulting in the need for quantitative exposure data on an age- and activity-specific basis. The ORETF has completed the field phase for multiple studies to measure the exposure to homeowners applying different formulation types and using various application equipment. Similar studies have also been completed for professional lawn care operators, although not covered under FQPA. However, the ORETF is now set to embark on the most difficult of its objectives. The question is how much potential exposure exists for people of various age groups who enter a lawn after it has been treated with a pesticide, the answer to which is predicated upon extensive knowledge of who is entering the lawn, how much time is spent on the lawn, how much bodily contact they have with the lawn, and so forth. Thus the question is extremely complex and a number of scientific efforts are underway in EPA, academia and industry. The ORETF is in the process of conducting it own survey over the next 15 months to characterize the activity patterns of specific age groups on turf, at an estimated cost of $1 million.
>
> "...The ORETF has committed a vast amount of monetary and temporal resources to address the issues of exposure from treated lawns, but needs the time to produce the data. *Producing the data for compounds that have been prematurely forced out of existence makes no sense.*
>
> "...In summary, it is our scientific judgment that the current default assumptions greatly overestimate exposure and that previous evaluations have not indicated that an imminent danger exists from outdoor exposure to pesticides in a residential setting...Therefore, all we are asking of the SAP and the various regulatory agencies is to allow adequate time to generate accurate and reliable exposure data that will provide a sound scientific basis for making informed risk judgments."

RED p. 61, par. 2 (risk assessments):

"The calculations presented in this section serve as the basis for both the short-term and intermediate-term post-application risk assessments...."

Gowan Response:
Given the discussion above regarding the RED p. 60, par. 5, Gowan does not believe that intermediate-term risk assessments are appropriate. We believe instead that acute and short-term risk assessments are appropriate for evaluating post-application risks. Inasmuch as the short-term NOEL is 11 times higher than the intermediate-term NOEL, calculations regarding risk will differ by an order of magnitude, depending on the assumed length of exposure.

"Short-term" is generally defined as 1 - 7 days. Again please note, however, that the short-term NOEL for bensulide is derived from 14 consecutive days of exposure (days 6 - 20 in a rat developmental toxicity study; cf. RED pp. 14 and 29). Therefore we consider the short-term NOEL to be appropriate for all exposures up through two weeks.

RED p. 68, last par. (dermal risk for handlers):
"Dermal risks for handlers were assessed using the short-term and intermediate-term toxicological endpoints."

Gowan Response:
The acute NOEL for bensulide is 15 mg/kg. The short-term (1 - 7 days) NOEL for bensulide is 5.5 mg/kg/day, whereas the intermediate-term (1 week to several months) NOEL is defined as 0.5 mg/kg/day [cf. RED p. 29]. We noted above that acute and short-term end-points are relevant to evaluating risk scenarios for handlers. However, it is not appropriate to conduct an intermediate-term toxicological assessment with bensulide since intermediate-term exposure to handlers never occurs.

The vast majority of agricultural applicators are exposed only one day per year. A few individuals involved in chemigation application on large commercial vegetable farms may be exposed two or three days per year. No agricultural applicator is exposed seven days per year.

Similarly, most grounds keepers on golf courses are exposed only one day per year. Some are exposed two days per year, with some months in between exposures, and a few may apply bensulide up to three times per year. We do not believe that any such individual is exposed to two consecutive days of exposure.

If bensulide is still used by professional lawn care applicators, these individuals could be exposed for a few consecutive days per year during a short period in the early spring. Please refer to our discussion above concerning the RED p. 41, par. 4 concerning various exposure scenarios. Some of the exposure equipment scenarios considered by the Agency are highly unlikely. It is our understanding that a label restriction against some of these scenarios would have no commercial

impact and would be acceptable to the affected registrants.

RED p. 71, par. 5 (intermediate-term occupational post-application exposure): "On turf in occupational settings, at an application rate of 12.5 pounds active ingredient per acre, MOEs did not equal or exceed 100 for activities on turf...."

Gowan Response:
We believe that three standard assumptions which the Agency has used are not applicable in this case due to the properties or use patterns of bensulide. These assumptions are as follows:

1. The Agency has assumed that residues on turf dissipate at the rate of 10 percent per day [cf. RED p. 60, par. 5]. We believe that initial residues will be lower than what the Agency has assumed because bensulide must be watered in order soon after application in order to be effective.

2. Secondly, as we noted earlier, we believe that residues on turf will not be present longer than about a week simply because grass is mowed. On golf greens and tees in particular, mowing occurs quite frequently and grass clippings are removed from the site. This will limit post application exposure on golf courses to short-term exposure; an intermediate-term exposure risk assessment, in our opinion, is not appropriate. We expect our turf foliar residue dissipation study to demonstrate this to the Agency.

3. Thirdly, we believe that the timing of applications to home lawns will generally preclude significant dermal exposure. The only bensulide product which can be purchased and applied by homeowners is Green Light Betasan 3.6 Granules, EPA Reg. No. 869-212. Its label states,

> "Applications of Betasan must precede emergence of weeds from the soil. Crabgrass will emerge from the soil from four to six weeks before it is visible above lawn sod. If weeds are visible above the soil, it is too late to apply Betasan."

In practice, this product is almost always applied very early in the spring before the lawn emerges from winter dormancy. At this time the weather is generally cold and the lawn is unattractive and uninviting for close contact. Direct contact of skin, except for hands, with the lawn at this time of year would be unusual.

The Green Light label also permits a second application during late summer or early fall. Lawns would be actively growing during this period and our comments would not apply. We understand that use at such time is extremely small, however, compared to use during late winter or early spring when lawns are dormant.

In any event, as we have noted, a turf dislodgeable residue study with bensulide is scheduled to begin on May 12, 1998. Results should be available well before the

Agency expects to conduct a cumulative risk assessment of the organophosphate pesticides. This study will permit a more accurate exposure assessment. As we noted above, we believe that it would be inappropriate for the Agency to immediately impose any risk mitigation measures based upon conclusions derived from default assumptions when significant new information will become available shortly. We therefore respectfully request that final decisions regarding risk mitigation be deferred until these data are available.

Again, we thank the Agency for the opportunity to comment on this draft RED chapter.

Sincerely,

Robert E. Hawk
Regulatory Affairs Manager

cc: Susan Jennings

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